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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,547	02/12/2002	Rory A.J. Curtis	MPI01-019P1RNM	6620

7590 10/15/2003

Millennium Pharmaceuticals, Inc.
75 Sidney Street
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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Offic Action Summary	Application No.	Applicant(s)	
	10/074,547	CURTIS, RORY A.J.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 12, drawn to an isolated nucleic acid, a recombinant vector comprising said nucleic acid, a recombinant host cell comprising said vector and a method of producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 8-10, drawn to an isolated polypeptide, classified in class 530, subclass 350.

III. Claim 11, drawn to isolated antibodies, classified in class 530, subclass, 387.9.

IV. Claims 13-15, 19-22, drawn to a method of identifying compounds that bind or that modulate the activity of a polypeptide, classified in class 435, subclass 7.1.

V. Claims 16-18, drawn to a method for detecting the presence of a nucleic acid molecule in sample by contacting the sample with a nucleic acid which hybridizes to said nucleic acid, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent use, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group II can be used other than to make the antibody of Group III, such as it

can be used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group I, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically.

Since the invention of Group I includes a method of using the nucleic acid for the production of the polypeptide of group II, inventions II and I are related as process of making and product made. However, the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Group II can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acid of Group I can be used in a method of producing the encoded protein or can be used therapeutically.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein of Group II can be used as antigens in the production of antibodies or can be used therapeutically.

Inventions IV-V are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Additional Restriction Requirement

2. The claims of Groups I and V are drawn to a multitude of nucleic acid molecules (SEQ ID Nos:1 or 3) and method of using said nucleic acid molecules. This constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the nucleic acids is independent and distinct because no common structural or functional properties are shared by these nucleic acids. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

In the event that Applicant elects the invention of Group I or V, Applicant is additionally required to elect a single nucleic acid sequence. This requirement is not to

be considered as a requirement of an election of species, since each of the compounds recited in alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
09 October 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600